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EXAMINER
RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/857,581	Applicant(s) FADER ET AL.	
	Examiner Delia M. Ramirez	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-19,26,28-33,44 and 45* is/are pending in the application.

4a) Of the above claim(s) *5-9 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-4,10-19,26,28-33,44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

Claims 1, 3-19, 26, 28-33, 44-45 are pending.

It is noted that the examination of the instant application has been assigned to a different Examiner in Group Art Unit 1652.

Applicant's election without traverse of Group I, claims 1, 3-19, 26, 28-33, 44-45 and election with traverse of Group u (SEQ ID NO: 66), in Paper No. 6, filed on 4/7/2003 is acknowledged.

Applicant's traverse is on the ground(s) that the polynucleotides of Groups a-t share a consensus sequence (i.e. a polynucleotide encoding the polypeptide of SEQ ID NO: 66; Group u). Applicants submit Appendix A to show that there are only 65 differences among the polypeptides encoded by the polynucleotides of Groups a-t and that all these polypeptides encode isoflavone synthases. Therefore, according to Applicants, there is unity of invention among all the polynucleotides of Groups a-t.

Applicant's arguments have been fully considered but are not deemed persuasive. While one could argue that the polynucleotides of Groups a-u share a common structure because the polypeptides they encode share a consensus sequence, i.e. SEQ ID NO: 66, it is noted that the consensus sequence is not among polynucleotides but rather polypeptides. Therefore, the "common structure", as described by Applicants, refers to the polypeptides encoded by the polynucleotides of Groups a-u and not the polynucleotides of Groups a-u. Furthermore, even if the polynucleotides of Groups a-u share a common structure, i.e. a polynucleotide encoding the polypeptide of SEQ ID NO: 66, the compounds are not regarded as being of similar nature

because all the alternatives do not share a common property or activity. Each of the polynucleotides in Groups a-t may be detected by different nucleic acid probes. It is noted that due to the degeneracy of the genetic code, a consensus polynucleotide which encompass all the polynucleotides of Groups a-u will have substantially less common structural elements than the consensus polypeptide of SEQ ID NO: 66 and the polypeptides of Appendix A. As such, a nucleic acid probe which would detect one polynucleotide may not detect another, even if they encode proteins of similar function. In addition, it is also noted that the common structure which Applicants assert is the technical feature linking Groups a-u is not considered a contribution over the prior art since Siminszky et al. (EMBL accession number AF022462, 1/8/1998; cited in the IDS) teaches a polynucleotide encoding the polypeptide of SEQ ID NO: 10 (Group b) as indicated in the specification, page 10, lines 1-5. As such, the technical feature linking Groups a-u lacks novelty and does not make a contribution over the prior art.

The requirement is deemed proper and therefore is made FINAL.

Applicants have requested a telephonic interview prior to the next office action. According to the record, a telephonic interview with Ms. Lori Beardell and the previous Examiner of record took place on 5/8/2003. Ms. Beardell reaffirmed the election of the invention of Group I and Group u. Therefore, examination on the merits will be performed on claims drawn to a polynucleotide encoding the polypeptide of SEQ ID NO: 66, host cells and vectors comprising said polynucleotide, as well as a method of altering the level of expression of isoflavone synthase in a host cell using said polynucleotide.

It is noted that some of the claims in Group I are directed to non-elected polynucleotides. Therefore, claims 5-8, drawn to the polynucleotide of SEQ ID NO: 1 or a polynucleotide

encoding the polypeptide of SEQ ID NO: 2, claim 9, drawn to the polynucleotide of SEQ ID NO: 1, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 47, 54, 56, 58, 60, and claim 45, drawn to a polynucleotide encoding a plant isoflavone synthase wherein the polynucleotide is isolated with a primer corresponding to the polynucleotides of SEQ ID NO: 1, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 47, 54, 56, 58, 60, are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Some of the elected claims are still partially drawn to non-elected inventions. Examination of such claims will be restricted to the subject matter elected, which in the instant case is a polynucleotide encoding the polypeptide of SEQ ID NO: 66. Applicants are requested to amend the claims accordingly in response to this Office Action.

Specification

1. The specification is objected to since the sequence listing in page 50 indicates residues at positions 293 and 294 of SEQ ID NO: 66 as "unsure", however in page 53, positions 292 and 293 are marked as "Xaa" whereas position 294 is an Ile residue.

2. The specification is objected to because of the recitation in page 42 of "Xaa_{293} is Glu or Asp". It is noted that according to Appendix A, provided by Applicants in Paper No. 6, position 293 is more likely to be a Gln or a His residue instead of a Glu or Asp residue as recited in the specification.

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional application No. of 60/117,769 filed on 01/27/1999, 60/144,783 filed on 07/20/1999, and 60/156,094 filed on 09/24/1999

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 1/8/2002 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

5. The drawings have been reviewed and are objected under 37 CFR 1.84 or 1.152. See attached Notice of Draftsperson's Patent Drawing Review. Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDOMENT of the application. In addition, if amendments to the specification are needed due to drawing corrections, Applicant is requested to submit such amendments while the case is being prosecuted to expedite the processing of the application.

Claim Objections

6. Claim 10 is objected to because said claims are partially drawn to non-elected inventions (i.e. SEQ ID NO: 1, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 47, 54, 56, 58, and 60).

For examination purposes, only the recitation of "SEQ ID NO: 66" will be considered.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1, 3-4, 10-11 and 45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims are drawn to a sequence which is not considered a product for the following reasons. As known in the art, a sequence is a graphical representation of the order in which nucleotides or amino acids are arranged in a polynucleotide or polypeptide. This is analogous to a formula for a chemical compound. It is suggested that the claims be amended to recite "nucleic acid" instead of "sequence" to obviate this rejection. Correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 3-4, 10-19, 26, 28-33, 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 1 is indefinite in the recitation of "Xaa_{293} is Glu or Asp" and "Xaa_{294} is Thr or Ile" for the following reasons. The paper sequence listing shows that position 294 of SEQ ID NO: 66 corresponds to an Ile residue, therefore no Xaa is present at that position. Furthermore, as indicated above, the residues which correspond to position 293 are more likely to be Gln or His based on Appendix A provided by Applicants in Paper No. 6, and not Glu or Asp, as recited in the claim. For examination purposes, no patentable weight will be given to the terms above. Correction is required.

12. Claims 1, 3-4, 11-12, 13, 26 (claims 10-11, 14-19, 28-33 dependent thereon) are indefinite in the recitation of "nucleic acid sequence encoding a polypeptide with isoflavone synthase activity", "chimeric sequence comprising the nucleic acid sequence", "host cell comprising the chimeric sequence", "host cell ...further comprising a second chimeric sequence comprising a nucleic acid sequence encoding a polypeptide", "transforming a host cell with the chimeric sequence", "transforming the host cell with a second chimeric sequence", or "expression of the chimeric sequence" for the following reasons. As indicated above, a sequence is a graphical representation of the order in which nucleotides or amino acids are arranged in a polynucleotide or a polypeptide. As such, it is unclear as to how a graphical representation can encode a polypeptide. Similarly, it is unclear as to how a host cell can comprise a graphical representation or how one can transform a host cell with a graphical representation. It is suggested that the terms as recited above be amended to recite "nucleic acid encoding a polypeptide with...", "a chimeric polynucleotide comprising the nucleic acid of ...", "host cell comprising the chimeric polynucleotide", "host cell further comprising a second chimeric polynucleotide", "transforming a host cell with the chimeric polynucleotide", "expression of the

chimeric polynucleotide", or similar. It is noted that, in addition to the suggested language, the instant claims as well as their dependent claims may have to be further amended for clarity and/or appropriate antecedent basis. For examination purposes, the suggested language will be used. Correction is required.

13. Claim 10 is indefinite in the recitation of "the isolated nucleic acid...of claim 1 encoding ....selected from the group consisting of SEQ ID NO: ....., and SEQ ID NO: 66" as it is unclear how the instant claim further limits claim 1. While the other members of the group may further limit claim 1, it is unclear how " SEQ ID NO: 66" further limits claim 1 since claim 1 is directed to a nucleic acid encoding the polypeptide of SEQ ID NO: 66 with specific limitations in regard to several positions within SEQ ID NO: 66 whereas claim 10 appears to be directed to a nucleic acid encoding the polypeptide of SEQ ID NO: 66 without these specific limitations. For examination purposes, claim 10 will be interpreted as being a duplicate of claim 1. Correction is required.

14. Claim 14 is indefinite in the recitation of "chimera containing the maize R region between the region encoding the C1 DNA binding domain and the C1 activation domain" as it is unclear and confusing. As written, it is unclear if (1) the maize R region is a region which is normally found between the region encoding the C1 DNA binding domain and the C1 activation domain" or (2) if the chimera comprises the C1 DNA binding domain, the C1 activation domain and the maize R region located in between these domains. Furthermore, it is unclear as to which C1 DNA binding domain is being referred to (i.e. source) or what is C1. It is suggested that if the intended meaning of the term is "chimera containing the maize R region, wherein the R region is a segment of the polynucleotide encoding the maize transcription factor C1 and

wherein said segment is that in between the region encoding the C1 DNA binding domain and the C1 activation domain", the claim be amended accordingly. For examination purposes, the suggested interpretation will be used. Correction is required.

15. Claim 26 is indefinite in the recitation of "(a) transforming....., (b) optionally transforming..., and (c) growing the transformed host cell produced in step (a) or step (b)..." as it is unclear and confusing. As written, it appears that the method comprises 3 steps, namely (a), (b) and (c). However, the term "optionally" appears to indicate that the method may comprise steps (a) or (b) and further comprise (c). It is suggested that if the intended method comprises steps (a) or (b) and further comprise (c), the claim be amended by combining the recitation of (a) and (b) in one step, for example, "(a) transforming a host cell with the chimeric..... or transforming a host cell with the chimeric polynucleotide of claim 1 and a second chimeric polynucleotide....; and (b) growing the transformed host cell produced in (a).....". In the alternative, the claim can be amended to recite "(a) transforming the host cell with the chimeric..of claim 1..... or (b) transforming the host cell with the chimeric..of claim 1 and a second chimeric polynucleotide; and further comprising growing the transformed host cell produced in....". Correction is required.

16. Claim 28 is indefinite in the recitation of "wherein the isoflavonoid" since the term "isoflavonoid" lacks antecedent basis. For examination purposes, claim 28 will be considered a duplicate of claim 26. Correction is required.

17. Claims 29-31 are indefinite in the recitation of "the method of claim 26 or claim 27" since claim 27 is now canceled. For examination purposes, the term "claim 27" will not be given patentable weight. Correction is required.

18. Claim 44 is indefinite in the recitation of "method of claim 41" since claim 41 is now canceled. For examination purposes, the claims will be interpreted as having the limitations of claim 41. If the claim is amended to recite the limitations recited in claim 41, it is noted that the terms "nucleic acid sequence encoding all or ....the amino acid sequence encoding a plant isoflavone synthase", "probing a cDNA....with the nucleic acid sequence", "sequencing the cDNA...sequence", "expression of isoflavone synthase mediated by the cDNA...sequence" are considered indefinite for the reasons set forth above in regard to claims 1, 3-4, 11-12, 13, 26 and their dependent claims. Correction is required.

19. Claim 44 is indefinite in the recitation in claim 41 of "a substantial portion" as this is a relative term not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For examination purposes, the term will be interpreted as "fragment of any size". Correction is required.

20. Claim 44 is indefinite in the recitation in claim 41 of "DNA clone that hybridizes with the nucleic acid sequence of..." for the following reasons. First, it is unclear which polynucleotide is claimed absent a statement of the conditions under which the hybridization reaction is performed. Nucleic acids which will hybridize under some hybridization conditions will not necessarily hybridize under different conditions. In addition, as known in the art, hybridization takes place with nucleic acid molecules and not with sequences. For examination purposes, the term "hybridizes with the nucleic acid sequence of.." will be interpreted as "hybridizes under any conditions with the nucleic acid of ....". Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

21. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

22. Claims 3-4 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3-4 and 44 are drawn to (1) a genus of polynucleotides encoding any isoflavone synthase, (2) a genus of polynucleotides encoding any isoflavone synthase wherein the polynucleotides do not have the sequence set forth in SEQ ID NO: 9, or (3) a genus of polynucleotides encoding any plant isoflavone synthase or fragment thereof wherein the polynucleotides hybridize under any conditions to a polynucleotide encoding the polypeptide of SEQ ID NO: 66 and wherein the polypeptide of SEQ ID NO: 66 comprises specific amino acids at specific positions. See claim rejections under 35 USC 112, second paragraph for claim interpretation. While the specification discloses several plant isoflavone synthases and it also discloses a consensus sequence for an isoflavone synthase, the specification fails to disclose which are the critical structural elements required in any polynucleotide which encodes an isoflavone synthase nor there is disclosure of which are the critical structural elements within the polypeptide of SEQ ID NO: 66 which are associated with isoflavone synthase activity.

The specification does not contain any disclosure of the structure of all nucleic acids included in the claimed genus. The genus of polynucleotides is a large variable genus with the potentiality of comprising many structurally distinct nucleic acids. In the instant case, claim 3 does not recite any structural feature common to the members of the genus. In regard to claim 44, while the claim requires that the polynucleotides hybridize to the polynucleotide of claim 1, this structural limitation is not sufficient to adequately describe the genus since, in the absence of hybridization conditions, a major portion of the structure is completely undefined and the specification does not provide the remaining structural features necessary for the members of the genus to be selected. The specification discloses a few species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one of skill in the art cannot reasonably conclude that Applicants had possession of the claimed invention at the time the instant application was filed.

23. Claims 3-4 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding the polypeptide of SEQ ID NO: 66 wherein said polypeptide can comprise specific amino acids as recited in claim 1, does not reasonably provide enablement for any polynucleotide encoding an isoflavone synthase, any polynucleotide not comprising SEQ ID NO: 9 which encodes any isoflavone synthase or any polynucleotide encoding a plant isoflavone synthase or fragment thereof, wherein the polynucleotide can hybridize under any conditions to the polynucleotide of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breath of the claims.

The scope of the claims, as described above, is not commensurate with the enablement provided in regard to the large number of polynucleotides of unknown structure encompassed by the claims. As indicated above, the specification is silent in regard to (1) the critical structural elements required in any polynucleotide which encodes an isoflavone synthase and (2) the critical structural elements within the polypeptide of SEQ ID NO: 66 which are associated with isoflavone synthase activity. Furthermore, the specification does not disclose which are the structural elements required in any polynucleotide which hybridizes under any conditions to the polynucleotide of claim 1 to encode a plant isoflavone synthase.

While one could argue that the polynucleotides of the instant claims are enabled since one can isolate these polynucleotides by sequence comparison using the polynucleotide/polypeptide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone should not be used to determine function and that small structural changes can drastically change function. Bork (Genome Research, 10:398-400, 2000) teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Witkowski et al. (Biochemistry 38:11643-11650, 1999)

teaches that one amino acid substitution transforms a β-ketoacyl synthase into a malonyl decarboxylase and completely eliminates β-ketoacyl synthase activity. Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* where found to be hydroxylases once tested for activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. (Science 282:1315-1317, 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase.

Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to display isoflavone synthase activity, and the unpredictability of the prior art in regard to function and structural homology (i.e. sequence homology), one of ordinary skill in the art would have to go through the burden of undue experimentation in order to screen and isolate those polynucleotides, as encompassed by the claim, which encode proteins having isoflavone synthase activity. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 1, 3-4, 10-12, 15, 26, 28-29, and 44 are rejected under 35 U.S.C. 102(a) as being anticipated by Steele et al. (Archives of Biochemistry and Biophysics, July 1, 1999; cited in the IDS). Steele et al. teaches a soy (Glycine max) isoflavone synthase and its corresponding polynucleotide. The polynucleotide of Steele et al. encodes the polypeptide of SEQ ID NO: 66 and meets each one of the limitations in regard to the required residues at the positions recited in claim 1, therefore anticipating claim 1 and 10 as written. See claim interpretation above. Alignments are provided for visualization purposes only. Note that limitations at positions 293 and 294 have not been considered for the reasons set forth above. Claim 44, which is directed to a polynucleotide obtained by probing a cDNA library or a genomic library with the nucleic acid of claim 1, is also anticipated by the polynucleotide of Steele et al. since the complementary strand of the polynucleotide of Steele et al. will detect its coding strand. Since claim 3 is directed to any polynucleotide encoding an isoflavone synthase, the polynucleotide of Steele et al. anticipate said claim as written. Claim 4, which is directed to any nucleic acid which encodes an isoflavone synthase which does not have the sequence set forth in SEQ ID NO: 9, is also anticipated by the polynucleotide of Steele et al. See, for example, position 453-455 of the polynucleotide of Steele et al., which encodes a Leu residue, as opposed to the polynucleotide of SEQ ID NO: 9 which encodes a Pro residue at the corresponding position in SEQ ID NO: 10 (140) according to the sequence listing.

Steele et al. also teach a baculovirus vector which comprises the polynucleotide, the transformation of insect cells with such vector and the expression of the isoflavone synthase (page 147, colum1, last paragraph). Claims 11, 12, and 15 are directed to the polynucleotide of claim 1 further comprising suitable regulatory elements, a transformed host cell, and a

transformed eukaryotic cell, respectively. Therefore, the baculovirus vector and transformed insect cells of Steele et al. anticipate such claims as written. Claims 26, 28-29 are directed to a method which comprises transforming a eukaryotic host cell with a nucleic acid of claim 11 and growing the host cell to express the synthase. Since Steele et al. teaches the transformation of Spodoptera cells (insect cells) with a baculovirus vector to express the soybean isoflavone synthase, the teachings of Steele et al. also anticipate claims 26, 28-29 as written.

25. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Siminszky et al. (EMBL accession number AF022462, 1/8/1998; cited in the IDS). The polynucleotide of Siminszky et al. encodes a soybean isoflavone synthase. Since claim 3 is directed to any polynucleotide encoding a plant isoflavone synthase, the teachings of Siminszky et al. anticipate the instant claim as written.

26. It is noted that SEQ ID NO: 66 was not disclosed in provisional application 60/117,769, which was filed on 1/27/1999.

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

28. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

29. Claims 17-19 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steele et al. (Archives of Biochemistry and Biophysics, July 1, 1999; cited in the IDS) in view of Siminszky et al. (Proc. Natl. Acad. Sci. 96:1750-1755, February 1999; cited in the IDS).

Claims 17-19 are drawn to a host cell transformed with the nucleic acid of claim 11 as described above, wherein the host cell is a plant cell, a soybean cell or a corn cell. Claims 30-33 are drawn to the method of claim 26 as described above wherein the host cell is a yeast cell, a plant cell, a soybean cell or a corn cell.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to transform a yeast cell, a plant cell, a soybean cell or a corn cell with a vector comprising the polynucleotide of Steele et al., in order to express the soybean isoflavone synthase. A person of ordinary skill in the art is motivated to construct a vector suitable for expression in these cells to express the soybean isoflavone synthase and obtain sufficient amounts of the synthase for further functional characterization studies. Transformation in yeast cells is desirable since this unicellular eukaryotic cell can provide glycosylation and its transformation is well known and widely used in the art. Transformation in any plant cell is also desirable since their glycosylation pattern is different from that of yeast and would provide a protein with a glycosylation pattern which is closer to its native form. One of ordinary skill in

the art has a reasonable expectation of success at transforming a yeast cell or plant cells, as recited in the claims, since Siminszky et al. teaches the transformation of yeast and tobacco cells with vectors comprising polynucleotides which encode P450 isozymes. Furthermore, transformation of yeast and plant cells is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Conclusion

30. No claim is in condition for allowance.

31. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

32. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 24, 2003

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1900~~ 1600